REMARKS

Claims 1, 3 and 5 through 8 are pending in the application.

Claim 1 has been amended to reflect advantageous embodiments in which carrier material is paper, a polymer or a composite material composed of paper, polymer or a thin metal foil or polymer and a thin metal foil. Support for this amendment can be found in the Application-as-filed, for example in Claim 3.

Claims 1, 5 and 6 have been amended to emphasize that the contaminating substances diffuse into the carrier material. Support for this amendment can be found in the Application-as-filed, for example on Page 3, lines 1 through 5.

Claims 1, 5 and 6 have been amended remove the extraneous term "undesired." Support for this amendment can be found in the Application-as-filed.

Claim 3 has been amended to depend from Claim 6. Support for this amendment can be found in the Application-as-filed.

Reexamination and reconsideration of this application, withdrawal of all rejections, and formal notification of the allowability of the pending claims are earnestly solicited in light of the remarks which follow.

Section 112 Rejection

Claims 1, 3, 7 and 8 stand rejected apparently because the disclosure as filed does not adequately name the contaminating substance removed by the instantly claimed method. The Application-as-filed indicates that substances to be removed by the methods of the invention include active ingredients, adjuvants and flavors used in the formation of sheet-like, wafer-like or film-like forms of drugs, confectionary, food or cosmetics. In that regard, the Examiner's attention is kindly directed to the Application-as-filed on Page 4, lines 11 through 13 and Page 1, lines 5 through 7. Applicants respectfully submit that the Application-as-filed on Page 3, lines 5 through 7 additionally notes breath freshening compounds and fragrances used for oral hygiene as specific exemplary contaminants that can be removed from carrier materials via the inventive methods. Applicants thus respectfully submit that the Application-as-filed clearly conveys to those skilled in the art that the inventors had possession of the claimed invention at the time the Application was filed, thus satisfying the written description requirement.

Applicants further respectfully submit that one of ordinary skill in the art could clearly immediately envisage potential contaminating materials within drug, food or cosmetic coatings used to form sheet-like or film-like forms of administration of drugs, confectionary, food, cosmetics and the like that could be removed from carrier materials via the inventive heating methods, in contrast to the urgings of the outstanding Office Action on Page 3, first partial paragraph.

Applicants also respectfully make of record that vaporization/sublimation temperatures are either generally known for food, drug, and cosmetics components or may be readily determined by one skilled in the art without performing undue experimentation using well known analytical techniques, in contrast to the urgings of the Office Action on Page 3, first partial paragraph.

Applicants additionally respectfully make of record that that the contaminant material need not be converted into a vapor at approximately 80 °C, in contrast to the further urgings within the Outstanding Office Action on Page 3, first partial paragraph. The Application-as-filed instead clearly indicates on Page 5, lines 1 through 2, that temperatures suitable for use in the decontamination methods of the instant invention can be "easily assessed" through "simple experiments" using conventional means and methods of chemical analysis. The Examiner's attention is also kindly directed to the Application-as-filed on Page 4, lines 21 through 31, describing the methodology for determining the appropriate temperature and time for thermal treatment.

Applicants likewise respectfully make of record that one skilled in the art could readily envisage which sheet-like or film-like food, drug, and cosmetic compositions are suitable for the instant invention without performing undue experimentation. For example, one skilled in the art would clearly understand whether a given food, drug or cosmetic contaminant would be "vaporized or sublimed at ambient pressure and approximately 80 C" or could readily determine such fact using well known analytical techniques, in contrast to the apparent urgings of the outstanding Office Action on Page 3, first partial paragraph.

Applicants thus respectfully submit that the Application-as-filed clearly conveys to those skilled in the art that the inventors had possession of the claimed invention at the time the Application was filed. Accordingly, Applicants respectfully request withdrawal of the foregoing rejection.

Claims 5 and 6 stand rejected over the limitation "other undesired substances." Without addressing the merits of the rejection and solely to advance prosecution of the above-referenced case, the phrase "other undesired substances" has been removed from Claims 5 and 6. Out of an abundance of caution, the foregoing phrase has been removed from Claim 1 as well. Accordingly, Applicants respectfully request withdrawal of the foregoing rejection.

The Claimed Invention is Patentable

in Light of the Art of Record

Claims 5 and 6 stand rejected over United States Patent No. 4,569,837 ("US 837") to Suzuki et al. in view of United States Patent Application Publication No. 2001/0006677 ("US 677") to McGinity et al.; United States Patent No. 2,486,258 ("US 258") to Chavannes; United States Patent No. 4,079,106 ("US 106") to Goldsworthy et al., and United States Patent No. 4,622,761 ("US 761") to Barth.

Claims 1, 3, and 7 stand rejected over the foregoing references and further in view of Lerdkanchanaporn et al. (Thermochimica Acta 2000 357-358:71-78) ("Thermochimica") and Lerdkanchanaporn et al. (Journal of Thermal Analysis 1887 49:879-886)("Thermal Analysis").

Claims 1 and 8 over US 837 in view of US 677, US 258, US 106 and further in view of United States Patent No. 4,978,836 (US 836) to Dieudonne et al. and United States Patent No. 5,112,220 ("US 220") to Wimberger et al.

It may be useful to briefly consider the invention before addressing the merits of the rejection.

Applicants respectfully reiterate that drugs, foods and cosmetics (hereinafter referred to as "consumables") are known for consumption in film-forms, and various production processes are known for their manufacture. Film-form consumables are generally manufactured on fully automated production lines by forming thin sheets of an active-ingredient film on a carrier material. In forming consumable films via a batch operation, the active-ingredient containing film is typically peeled off of the carrier material and the separated carrier material is taken up onto a reel.

Unfortunately, Applicants have determined that the active-ingredient (as well as any additional adjuvants or other coating compounds) can diffuse into the carrier material during production. The carrier material is then contaminated by these substances, up to their respective degree of saturation, and has heretofore been unavailable for reuse. The required disposal such contaminated carrier material presents both an economic and environmental challenge.

Surprisingly, Applicants have found that drug, food and cosmetic contaminants can be removed from carrier materials using simple thermal treatments performed at moderate temperatures and dwell times, such as at a temperature of approximately 80 °C for approximately 0.5 to 6 minutes, and the evaporated contaminants can then be permanently disposed of by feeding the evaporated contaminants to a thermal after-burner using controlled air circulation, as recited in the claimed invention.

In particularly advantageous embodiments, the carrier material is paper, a polymer or a composite material composed of paper, polymer or a thin metal foil or polymer and a thin metal foil, as recited in Claim 1 as-amended.

Altogether unexpectedly, the foregoing thermal decontamination does not significantly detrimentally impact the physical properties of the recited carrier materials. Hence the decontaminated carrier material, also referred to as neutralized carrier material, may then be reused as a carrier within the active-ingredient film forming process, as further recited in the claimed invention.

Applicants respectfully reiterate that the cited references do not teach or suggest the claimed invention.

The cited references simply do not recognize the removal of contaminants that have diffused into a carrier material as an issue, much less recommend a thermal treatment to address such diffusion. Consequently, there would have been no motivation to have incorporated an

additional thermal treatment, as the problem was unknown. *In re Omeprazole Patent Litigation*, 536 F.3d 1361 (Fed. Cir. 2008)(non-obviousness of solution to previously unknown problem).

US 837, the sole reference directed to film-form drugs, is altogether silent as to any contamination issues associated with its belt. The "continuous carrier" used to form the decorative films of US 258 has been coated "so that is not attacked by components within the coating," although its surface may be mechanically cleaned via a driven brush. US 106 similarly teaches a wax or release coated belt for forming its polyurethane foam whose surface may be cleaned mechanically.

Consequently, the combination of references does not teach or suggest the removal of diffused contaminants into a carrier material, and most certainly not the removal of drug, food or cosmetic contaminants from a carrier material formed from paper, polymer or metal foil via thermal treatment, as recited in Claim 1 as-amended. The combination instead merely teaches the use of coatings to protect carriers, along with mechanical surface cleaning.

US 837 is directed to pharmaceutical preparations for periodontal disease. (Col. 2, lines 16 – 18). US 837 notes that its medicinal agent is dissolved in polymer, cast and dried. (Col. 5, lines 40 – 45). US 837 generically notes that its compositions may be cast onto a glass plate, metal plate, drum or "endless belt." (Col. 6, lines 3 – 8). The working examples of US 837 cast the medicinal compositions onto a glass plate or subject them to compression molding. (Col. 6, line 53 through Col. 10, line 55).

US 837, merely noting the casting of polymers on "belts", does not teach or suggest the diffusional contamination of a carrier material, and most certainly not the removal of drug, food or cosmetic contaminants from a carrier material formed from paper, polymer or metal foil via thermal treatment, as recited in Claim 1 as-amended.

US 677 is merely directed to holt melt extruded effervescent films having a controlled rate of disintegration. (Para. 0001). The impetus of US 677 is that hot-melt extrusion allows for

extremely short exposure times to elevated temperatures than batchwise hot-melt methods, and further does not require solvents. (Para. 0025). The films of US 677 are formed by hot-melt extruding the effervescent mixture and either rolling the resulting film extrudant directly into a tape or cutting it into pieces. (Para. 0095).

US 677, solely directed to hot melt films, does not teach or suggest carrier materials, much less the diffusional contamination of carrier materials, and most certainly not the removal of drug, food or cosmetic contaminants from carrier materials formed from paper, polymer or metal foil via thermal treatment, as recited in Claim 1 as-amended.

US 258 is directed to films having an embedded design. (Col. 1, lines 23 – 30). The films of US 258 are formed on a "continuous carrier" that has been coated so that" it will not be attacked" by components within the coating. (Col. 3, lines 29 – 37). US 258 expressly teaches cleaning of its carrier surface with a driven buffing brush. (Col. 6, lines 52 – 62).

US 258 does not teach or suggest the removal of diffused contaminants from its carrier material, and most certainly not the removal of drug, food or cosmetic contaminants from a carrier material formed from paper, polymer or metal foil via thermal treatment, as recited in the Claim 1 as-amended. US 258 instead expressly teaches the incorporation of carrier coatings that protect the carrier from coating components, along with a driven buffing brush to provide mechanical cleaning of the carrier surface. Applicants further respectfully make of record that the Office Action's urging on Page 13, first partial paragraph, that contamination "must also occur" in US 258 is purely a conclusory statement, particularly in light of US 258's express teaching that its carrier has been coated so as to protect the carrier from coating components.

Applicants respectfully reiterate that US 106 is directed to the continuous fabrication of polyurethane foam insulation. (Col. 1, lines 55 – 60). Liquid/molten polymer is applied to three dimensional filaments disposed on the surface of a belt which has been coated with a wax or an equivalent release agent. (Col. 2, lines 25 - 28 and 44 – 45). After curing sufficiently, the

foamed material is "cut" from the belt. (Col. 2, lines 39 – 41). After cutting the cured/dryed material from the belt, the belt is "cleaned" and subsequently re-coated with a wax or release agent. (Col. 2, lines 43 – 47) Suitable cleaning methods include mechanical cleaning and solvent cleaning. (Col. 2, line 44).

US 106, teaching a wax or release coated belt, does not teach or suggest the removal of diffused contaminants from a carrier material, and most certainly not the removal of drug, food or cosmetic contaminants from a carrier material formed from paper, polymer or metal foil via thermal treatment, as recited in Claim 1 as-amended. Applicants respectfully submit that US 106, teaching a wax or release coated belt, merely removes debris from the surface of its belt, rather than contaminants that have diffused into the belt. In that regard, Applicants further respectfully submit that US 106 clearly suggests the incorporation of coatings to avoid belt contamination. Applicants take this opportunity to respectfully make of record that the urgings of the outstanding Office Action on Page 7, first full paragraph and Page 13, last full paragraph that the cleaning of US 106 removes essentially all contaminants is conclusory.

US 761 is directed to particular dryers that have been contaminated by volatilized medicinal residues. (Col. 1, lines 33 – 38). US 761 is particularly directed to TTS dryer systems that avoid "contamination from residues of previous charges" and prevent the escape of substances into the atmosphere. (Col. 1, lines 57 – 64). The dryers of US 761 have cup-shaped, rounded wall elements enabling rapid disassembly for cleaning. (Col. 2, lines 31 – 49). A "self-supporting" sheet of material is guided through the dryer. (Col. 4, lines 35 – 40). US 761 further teaches that solvents and medicinal residues escaping as the sheet of material is dried may be burned. (Col. 3, lines 49 – 51).

US 761, merely drying a self-supporting material, does not teach or suggest a carrier material, much less the diffusional contamination of a carrier material, and most certainly not the removal of drug, food or cosmetic contaminants from a carrier material formed from paper, polymer or metal foil via thermal treatment, as recited in Claim 1 as-amended.

The tertiary references do not cure the deficiencies in the foregoing references.

Thermochimica merely profiles the evaporation behavior of of ibuprofen between its melting point and boiling point. Thermal Analysis studies the effect of starch on the evaporation onset temperature.

Thermochimica and Thermal Analysis similarly do not teach or suggest carrier materials, much less the diffusional contamination of carrier materials, and most certainly not the removal of drug, food or cosmetic contaminants from carrier materials formed from paper, polymer or metal foil via thermal treatment, as recited in Claim 1 as-amended.

Applicants respectfully submit that there would have been no motivation to have combined US 837, US 677, US 258, US 106, US 761, Thermochimica and Thermal Analysis. Applicants further respectfully submit that the arts of cast films, hot melt films, foam insulation, decorative films and transdermal therapeutic devices are incredibly divergent.

However, even if the foregoing references were combined (which Applicants did not do), the claimed invention would not have resulted.

None of the cited references teaches or suggests the removal of drug, food or cosmetic contaminants from a carrier material formed from paper, polymer or metal foil via thermal treatment, as recited in the claims as-amended. The only express teaching as to potential coating interaction with carriers is US 258, which instead expressly teaches the incorporation of carrier coatings to avoid the coating component's "attacking" the carrier, along with a driven buffing brush to provide mechanical cleaning of the carrier surface. US 106 likewise teaches a wax or release coated belt.

US 837, the sole reference directed to film-form drugs, is altogether silent as to any contamination issues associated with its endless belt. As noted above, the "continuous carrier" used to form the decorative films of US 258 has been coated so that "it will not be attacked" by

components within the coating, although its surface may be mechanically cleaned via a driven brush. US 106 similarly teaches a wax or release coated belt for forming its polyurethane foam whose surface may likewise be cleaned mechanically. US 677, directed to hot melt extruded films, does not teach or suggest a carrier material. US 761, merely drying a self-supporting material, likewise does not teach or suggest a carrier material. Thermochimica and Thermal Analysis, both directed to ibuprofen properties, also fail to teach or suggest a carrier material.

Consequently, the combination of references at bests suggests the incorporation of a coating to protect a carrier material, along with driven brushes to mechanically clean the carrier surface.

The combination thus can not teach or suggest the inventive decontamination of carrier material via thermal treatment performed at a temperature of approximately 80 °C and a period of time approximately 0.5 to 6 minutes, much less that such decontamination would be sufficient to remove essentially all the drug, food or cosmetic contaminants from the carrier material, as further recited in Claim 1.

The combination thus likewise fails to teach or suggest passing contaminated carrier material through a thermal treatment zone at a temperature and during a period of time sufficient to remove essentially all of the drug, food or cosmetic contaminating substances that have diffused into the carrier material, as recited in Claims 5 and 6.

Applicants thus respectfully submit that the claimed invention is patentable in light of US 837, US 677, US 258, US 106, US 761, Thermochimica and Thermal Analysis, considered either alone or in any combination.

As the beneficial aspects of Claim 3 have been incorporated into Claim 1, Applicants respectfully submit that the claimed invention is likewise patentable in further of US 836 and US 220, as kindly indicated by the Examiner. Out of an abundance of caution, however, Applicants

respectfully submit that US 836 and US 220 likewise fail to teach or suggest the claimed invention.

CONCLUSION

It is respectfully submitted that Applicants have made a significant and important contribution to the art, which is neither disclosed nor suggested in the art. It is believed that all of pending Claims 1, 3 and 5 through 8 are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned if any questions remain to expedite examination of this application.

It is not believed that extensions of time or fees are required, beyond those which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time and/or fees are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required is hereby authorized to be charged to Deposit Account No. 50-2193.

Respectfully submitted,

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